



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

cd

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

09/932,512 08/17/2001 Thomas E. Borillo 593/004 6335

1473 7590 09/29/2003

FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020-1105

EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/29/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,512

Applicant(s)

BORILLO ET AL.

Examiner

Victor X Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 August 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 and 21-49 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 and 18-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Art Unit: 3731

DETAILED ACTION

Election/Restrictions

1. This application contains claims 13-17 and 21-49 drawn to non-elected inventions. In Paper No. 9, dated August 18, 2003, applicant elected to prosecute Group I, Species I. Furthermore, it was stated that all claims in Group I read upon the elected species. However, claims 22-26 do not read upon the elected species. Claims 22-26 are drawn to Species V which illustrates a device has inflatable anchors. Therefore, non-elected claims 13-17 and 21-49 are withdrawn from further consideration.

The requirement is deemed proper and is therefore made **Final**.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18, line 6, it is unclear what is meant by "an expandable membrane" and how it relates to a system for filtering blood flowing through an atrial appendage. Furthermore, there is no support the term "an expandable membrane" in the specification or in the drawing.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3731

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12 and 18-20 are rejected under 35 U.S.C. 102 (e) as being anticipated by Lesh et al. (U.S. 6,152,144).

Lesh et al show in Figs. 6-7, 9, col. 1, lines 64-67 and col. 2, lines 1-67, a device having all the limitations of claims 1 and 18, including: a tube (72) has a first closed end that comprises a blood filter (63); an expandable structure (65) has a collapsed configuration and an expanded configuration; and wherein the device is inserted in the appendage while the expandable structure (65) is in the collapsed configuration.

Regarding claims 2-4, wherein the tube (72) has a cylindrical shape; and wherein the tube comprises a blood filter (63).

Regarding claims 5-6, wherein the expandable structure (65) is self-expanding; and wherein the expandable structure expands from the collapsed configuration to the expanded configuration by an inflatable balloon (labeled in col. 9, lines 29-41).

Regarding claims 7-9, wherein the device further comprises a self-sealing opening (labeled in col. 10, lines 3-9) for withdrawing the inflatable balloon.

Regarding claims 10-12 and 19, wherein the tube comprises elastomeric material, braided material and woven material (col. 2, lines 30-67 and col. 3, lines 1-9); and wherein the filter (63) comprises holes to harmful-size emboli. Regarding claim 20, the filter element is made of material that is less elastic than the expandable membrane (inherent

Art Unit: 3731

feature, item 63 is made from polyurethanes, polyethylene, labeled in col. 2, lines 36-45, col. 3, lines 4-10 and col. 9, lines 51-57).

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

| | |
|---------------------------------------|--------------------------------------|
| U.S. Pat. No. 6,551,303 to Van Tassel | U.S. Pat. No. 6,270,490 to Hahnen |
| U.S. Pat. No. 6,319,251 to Tu | U.S. Pat. No. 6,547,760 to Samson |
| U.S. Pat. No. 5,865,791 to Whyne | U.S. Pat. No. 6,447,530 to Ostrovsky |
| U.S. Pat. No. 5,366,504 to Andersen | U.S. Pat. No. 6,231,589 to Wessman |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

vn vn
September 19, 2003


KEVIN T. TRUONG
PRIMARY EXAMINER

9/22/03